## SECTION 2- 510(K) SUMMARY

AUG 3 0 2007

**Name and Address of Applicant**
Nihon Kohden America, Inc.
90 Icon Street
Foothill Ranch, CA 92610

**Contact:**
Jack Coggan
Director, Regulatory Affairs
(949) 580-1555 ex. 3325
Fax: (949) 580-1550

- **Trade Name:** The ECG-1250A Series Cardiofax S and ECG-1350A Series Cardiofax M Electrocardiographs.

- **Common or usual Name:** Electrocardiograph/ECG

- **Classification Name:** The devices have been classified as Class II by the Division of Cardiovascular Device Classification Panel under 21 CFR Part 870.2340 Electrocardiograph per 74 LOS.

- **Legally Marketed Predicate:** Nihon Kohden ECG-1500A per 510(k) # 052511, commercial distribution certification dated May 24, 2006 and ECG-9130K per 510(k) #984504 commercial distribution certification dated April 15, 1999.

**Intended Use:** The Nihon Kohden ECG-1250A and ECG-1350A devices are intended for medical purposes to process the electrical signals transmitted through two or more electrocardiograph electrodes and to produce a visual display and/or prepare a record of the electrical signals produced by the heart. The product is a portable ECG acquisition terminal, which measures up to 12 lead ECG waveforms. You can record the resting ECG waveforms automatically or manually. In the automatic recording mode, ECG analysis is automatically performed and after ECG waveforms are recorded, the ECG analysis result is automatically printed.

**A summary of the technological characteristics of the device compared to the predicate device:** The ECG-1250A and ECG-1350A have a color LCD screen, which allows you to preview 2.8 seconds of 12 lead ECG waveforms. The devices also include data transmission through wired LAN or wireless LAN to personal computers or another electrocardiographs, prepares a full-page file up to 12 channels on 210 mm recording paper for the ECG-1350A and up to 6 channels on 110mm recording paper on the ECG-1250A, the device is compact, lightweight and easy to carry. The ECG-1350A's A4 notebook weighs 3.9kg without battery or recording paper. The ECG-1250A's A4 notebook weighs 2.0 kg without battery or recording paper.
The products are similar to Nihon Kohden predicate devices ECG-1500A and ECG-9130K in providing waveform, patient information, recording settings, operation mode, heart rate, QRS Sync mark error message, electrode detachment and noise. See attachment # 5 for comparison of the ECG-1250A and ECG-1350A to the predicate devices ECG-1500A and ECG-9130K.

**Performance Testing**

- The device is not sterile.

- The devices comply with the IEC-60601-1 standard and sub-clause 56.3 (c) implemented by 21 CFR Part 868 Performance Standard for Electrode Lead Wires and Patient Cables.

- The devices were subjected to tests including environment, vibration, impact and drop. Refer to the post qualification test report for ECG-1250A Series (Report No. 1667) and ECG-1350A series (report no.1785). The EMC test including EMI, flicker, static, emission immunity, burst, surge, conductive immunity, voltage dip and operator's manual check. Refer to the post qualification test report for ECG-1350A series test report 1667 and ECG-1250A Series test report 1785. Safety test was conducted only for display test using ECG-1250P and ECG-1350P as prototypes. The test results confirmed that the device performed within specifications.

- Therefore, based on the above, Nihon Kohden believes that the ECG-1250A series Cardiofax S and ECG-1350A Series Cardiofax M Electrocardiographs are substantially equivalent to the ECG-1500A and ECG-9130A products.

## SECTION 3 – PROPOSED LABELING

**A. Intended Use**

The ECG-1250A Series Cardiofax S and ECG-1350A Series Cardiofax M Electrocardiographs are intended for medical purposes to process the electrical signals transmitted through electrocardiograph electrodes and to produce a record of the electrical signals produced by the heart.

**B. Device Labels**

The proposed product labels for the devices are located in attachment #2.

**C. Proposed Packaging**

Proposed packaging for the devices ECG-1250A Series Cardiofax S and ECG-1350A Series Cardiofax M Electrocardiographs are presented in Attachment #3..

**D. Instructions for Use**

The proposed instructions for use are provided with each package device and are presented in Attachment #15.

**E. Advertisement/Promotional Literature**

To date, no advertisement or promotional literature for ECG-1250A Series Cardiofax S and 1350A Series Cardiofax M Electrocardiographs have been created for distribution in the United States.

**F. Contraindications, Precautions & Warnings**

Warnings and cautions are listed in the Operator's Manual as shown in Attachment #4.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 3 0 2007

Nihon Kohden America, Inc.
c/o Mr. Jack Coggan
Regulatory Affairs Director
90 Icon Street
Foothill Ranch, CA 92610

Re: K072217
ECG-1250A Series Cardiofax S and ECG-1350A Series Cardiofax M
Regulation Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph
Regulatory Class: Class II (two)
Product Code: DPS
Dated: Undated
Received: August 9, 2007

Dear Mr. Coggan:

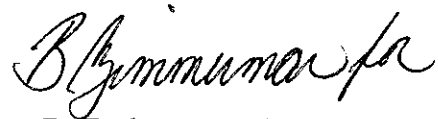
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

## G. Indications for Use Statement:

510(K) Number (if known): K072217

Device Name: ECG-1250A Cardiofax S and ECG-1350A Cardiofax M

Indications for Use:

The ECG-1250A Series Cardiofax S and ECG-1350A Series Cardiofax M Electrocardiographs are intended to monitor the patient's heart rate electrically, the devices have been developed as the devices to select the operators, amplify, record or measure the electric potential captured by the electrodes attached to the patient's thoracic and extremities parts. Based on the information output by the devices, the devices will help the doctors for their cardiovascular diagnostication.

For non-interpretive applications, the ECG-1250A Series Cardiofax S and ECG-1350A Series Cardiofax M Electrocardiographs are intended for use with a full range of patient populations as determined by a clinician.

The devices also provide an interpretive ECG program intended for use with patients are 3 years and older. The interpretation program is intended to provide an assessment of ECG waveform rhythm and morphology to assist the physician in diagnosis. Assessments provided by the interpretation program are not intended as the sole basis for diagnosis. Qualified physicians trained in electrocardiography recommend all assessments provided by the interpretation programs for review.

Prescription Use ___X_____ AND/OR Over The Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K072217

**CONCURRENCE OF CDRH, OFFICE OF DEVICE EVALUATION (ODE)**